

Jerry G. Blaivas, M.D.

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SUPERIOR COURT
J.D. OF WATERBURY, CONNECTICUT
COMPLEX LITIGATION DOCKET
- - -

MARY BETH FARRELL, et :
al, :
 :
Plaintiffs, :
 : DOCKET NO.
v. : X06-UWY-CV-11
 : -6014102-S
JOHNSON & JOHNSON, et :
al, :
 :
Defendants. :

- - -
August 13, 2015
- - -

Oral deposition of
JERRY G. BLAIVAS, M.D., taken pursuant to
notice, was held at the law offices of
Shipman & Goodwin, 300 Atlantic Avenue,
Stamford, Connecticut, beginning at 9:10
a.m., on the above date, before Michelle
L. Gray, a Registered Professional
Reporter, Certified Shorthand Reporter
and Notary Public.

- - -
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1 are you collecting pathology reports?

2 A. No. Materials. This is all
3 original research. He does all of the
4 pathology so this has nothing to do with
5 reports.

6 Q. He's collecting pathologic
7 samples and he's looking at them, right?

8 A. Yes.

9 Q. And then you two are
10 collaborating on this manuscript but it's
11 not yet done?

12 A. The research isn't done --
13 isn't complete.

14 Q. Are you the one looking at
15 the mesh under the microscope?

16 A. No. He does that.

17 Q. Pathology is not your area,
18 right?

19 A. Correct.

20 Q. What is your role?

21 A. We're starting to send him
22 specimens. You'll be happy to know that
23 the last specimen was a Prolift that I
24 excised last Monday. We'll send that to

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1 **Q.** So I guess now it makes
2 sense. The article that you're working
3 on with him, or the research, is
4 histopathology. You're looking at the
5 mesh that's been embedded in the
6 paraffin.

7 **A.** Yes. You know, actually I'm
8 going to have to correct that. I'm not
9 sure. This was over a year ago when we
10 started to do it. It makes more sense to
11 send him whole pieces. I'm sorry. I
12 just don't remember.

13 **Q.** Okay. Thank you for
14 correcting that. I'd rather that than
15 you tell me something that you're not
16 sure of.

17 Because you're not a
18 pathologist and you're not in the
19 business of looking at mesh under a
20 microscope, would you leave the
21 interpretation of what is there to
22 others?

23 **A.** Yes.

24 **Q.** Doctor, you're getting

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1 **Q.** Do you have any opinions
2 about mesh degradation or is that beyond
3 your specialty?

4 **A.** I have a -- my opinion --
5 yes, I do have opinions.

6 **Q.** What are they?

7 **A.** That I would say that it
8 more likely than not happens in some
9 instances.

10 **Q.** What do you mean by
11 degradation?

12 **A.** I mean, the -- the coating
13 of the mesh sort of falls -- at the
14 microscopic level, falls off, develops
15 cracks and fissures. And different
16 additives that are used in the process of
17 making the mesh can sort of leech out and
18 can potentially cause either inflammation
19 or other -- or further the process of
20 degradation that can weaken the mesh, and
21 then there's theoretic considerations
22 that it could cause problems in the
23 future.

24 **Q.** Is there any evidence in

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1 this case that Mary Beth Farrell's mesh,
2 either the Prolene Soft mesh that was
3 removed, or the Monarc sling, degraded?

4 MS. FUSCO: Objection.

5 THE WITNESS: Well, I don't
6 think anything was done to
7 determine that. That would
8 require electron microscopy.
9 Unless someone has looked at it
10 you wouldn't be able to tell.

11 BY MS. MAIMBOURG:

12 Q. So as of this point, the
13 answer is you don't know?

14 A. Correct.

15 Q. If degradation occurred, how
16 soon would you expect it to happen?

17 A. I couldn't -- I mean, I
18 think the longer it's in the body, the
19 more likely it is to happen. But I
20 couldn't answer that question.

21 Q. Is this something that would
22 be within the expertise of a biomaterials
23 expert?

24 MS. FUSCO: Objection.

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1 THE WITNESS: I think a
2 combination of biomaterials and
3 pathology, my gut says.

4 BY MS. MAIMBOURG:

5 Q. And since you have an
6 expertise in urogynecology and urology,
7 that's been the focus of your career,
8 right?

9 A. Yes. A focus.

10 Q. A focus.

11 Have you had a focus in your
12 career on biomaterials and pathology?

13 A. No.

14 Q. Do you feel more comfortable
15 deferring to an expert in one of those
16 fields to talk about degradation and
17 thereby saving me another two pages of
18 outline questions?

19 A. Absolutely.

20 Q. I said that with a smile.

21 MS. FUSCO: Can we take a
22 break?

23 (Short break.)

24 MS. MAIMBOURG: What was my

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1 know, we would check -- we would ask a
2 question whether something needed to be
3 in or not.

4 Q. Was that in connection with
5 the collagen 15 years ago and then the
6 nocturia a year or so ago?

7 A. No, that wasn't a device.
8 That was also another drug. That was
9 with some anti-cholinergic manufacturers.
10 Novartis was one. And Pfizer was
11 another. I was on the panel.

12 Q. Do you understand or know if
13 there are different regulations for drugs
14 and devices in terms of what must be in
15 warnings?

16 A. Yes, there are different. I
17 don't know what they are, but I know
18 there are different.

19 Q. Do you consider yourself an
20 expert in developing warnings and labels
21 for medical devices?

22 A. I do not.

23 Q. Are you familiar with the
24 federal regulations that govern IFUs,